Three dimensional virtual surgical planning for patient specific osteosynthesis and devices in oral and maxillofacial surgery. A new era.

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CHAPTER 7

SPLINTLESS SURGERY USING PATIENT SPECIFIC OSTEOSYNTHESIS IN LE FORT I OSTEOTOMIES: A RANDOMIZED CONTROLLED MULTI-CENTRE TRIAL

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THIS CHAPTER IS SUBMITTED TO

THE INTERNATIONAL JOURNAL OF ORAL AND MAXILLOFACIAL SURGERY AT THE MOMENT OF PREPARING THIS THESIS.

ABSTRACT

The accuracy of orthognathic surgery has improved with three-dimensional virtual planning. The translation of the planning towards the surgical result is reported to fluctuate by >2mm. Our randomised controlled multi-centre trial aims to objectify whether the use of splintless patient specific osteosynthesis can improve the accuracy of maxillary translations. Patients requiring a Le Fort I osteotomy were included in the trial. The intervention group was treated using patient specific osteosynthesis and the control group with conventional osteosynthesis and splint-based positioning. Fifty-eight patients completed the study protocol, 27 in the patient specific osteosynthesis group and 31 in the control group. The per protocol median anteroposterior deviation was found to be 1.05mm (IQR: 0.45-2.72mm) in the patient specific osteosynthesis group and 1.74mm (IQR: 1.02-3.02mm) in the control group. The cranial-caudal deviation was 0.87mm (IQR: 0.49-1.44mm) in the patient specific osteosynthesis group and 0.98mm (IQR: 0.28-2.10mm) in the control group whereas the left-right translation deviation was 0.46mm (IQR: 0.19-0.96mm) in the patient specific osteosynthesis group and 1.07mm (IQR: 0.62-1.55mm) in the control group. The splintless patient specific osteosynthesis method improves the accuracy in maxillary translations in orthognathic surgery and is clinical relevant in planned anteroposterior translations of more than 3,70 mm.

This randomized controlled trial was registered in the Netherlands Trial Registry under: NTR5324

INTRODUCTION

Orthognathic three-dimensional virtual surgical planning (3D VSP) has contributed to the improvement in the accuracy and predictability of the outcomes. In addition, 3D VSP allows for extensive pre-operative simulation of surgical options[1]. Positioning of the maxilla during a Le Fort I osteotomy is usually guided by a splint [2, 3], supported by intra- and/or extra oral reference points [3].

The use of 3D printed or milled splints, based on the VSP is reported to increase accuracy, but they do not change the translation of the planning towards the surgical procedure [4-8]. The translation of the planning to the surgical procedure remains variable and is reported to fluctuate >2mm from the planning [3, 5, 9-11]. This is due to errors in seating the splint as well as the position of the condyles when the patient is in a supine position and, difficulties in measuring the exact vertical positioning of the maxilla [6, 11]. To overcome these translation errors, several splintless procedures have been developed to translate the maxilla to the planned position, using patient specific osteosynthesis (PSO) [4, 6, 10, 14, 15]. However, the reports only include case reports and patient series; they lack a control group providing systematic comparison with the conventional splint-based workflows. The use of a PSOs for maxillary fixation requires a surgical guide or template that indicates the correct position of the screw holes and location of the Le Fort I osteotomy. Both bone- and tooth borne supported template methods have been described [14, 16-18]. The use of PSOs potentially provides high accurate translation of the 3D VSP to the surgical procedure, and thereby translation of the maxilla to the planned position [19]. There is no reported consensus as to which direction or amount of translation the maxilla benefits most from the application of PSOs. It is suggested that a vertical translation of the maxilla can be performed accurately due to vertical guidance and independence of the condylar seating [10, 19].

The PSO concept was already reported by our group in 2016 after successful application in a pilot study [6]. In this prospective randomized controlled multi-centre trial the PSO group (intervention) is compared with a control group after applying manually contoured osteosynthesis material (OSM) to the maxilla, guided by a 3D VSP-based positioning splint.

The primary outcome measure is the deviation, in millimetres, translation and degrees rotation, of the planned vs. the achieved maxillary position. In addition, the surgeon's satisfaction is registered on applying the PSO method. This study aims to objectify whether there is an improvement in maxillary translation accuracy in three dimensions, by the use of PSOs in Le-Fort I osteotomies and, if there is, to identify specific indications for the use of PSOs.

MATERIALS AND METHODS

Study population

This randomized controlled multi-centre trial was performed at the departments of oral and maxillofacial surgery of the University Medical Center Groningen, the Netherlands and the Martini Hospital Groningen, the Netherlands between August 2015 and October 2018. The trial was approved by the local medical ethics board under file number: METc 2015/084. A total sample of 64 patients was identified. The sample size per group was calculated based on data found from our group's pilot study [6] whereby two additional patients were added to each group to overcome loss-to-follow up or protocol violations. Only patients who had completed the study protocol were included in the final per protocol (PP) data analysis. In addition an intention to treat (ITT) analysis was performed.

The procedure was reported as a failure if the surgeon decided to switch from PSO to conventional OSM during surgery. It was agreed that after three failures, the PSOs should be critically redesigned and five failures were defined as being a stop-sign for the study.

Patient inclusion criteria were: they were due to receive a non-segmental Le Fort I osteotomy as part of their orthognathic surgery; could complete the routine 3D diagnostic 3D VSP work-up; and were at least 18 years of age.

Patient exclusion criteria were: they did not agree to participate in the trial; pregnancy; they had a known allergy to titanium; and they required a segmental Le Fort I osteotomy.

Eligible patients who were in the presurgical phase of their combined orthodontic-surgical treatment were asked to participate during the outpatient orthognathic consultations. Included patients were assigned to either the control group or the intervention group by means of blocked randomization. A unique blocked (block size 4) randomization list was created by the sealed envelope online tool [20].

Intervention

A 3D VSP was performed for every patient according to the triple scan protocol, as described by Swennen et al. [21]. This, including the final position of the fixation screws for the PSO, was performed in the UMCG by a technical physician (JK) and an oral and maxillofacial surgeon (JJ or RS). PSOs and accessory 3D printed drilling/osteotomy guides where designed for the patients assigned to the PSO group. The PSOs where milled out of medical grade titanium and the resin based drilling guides where designed and fabricated by Createch Medical (Createch, Mendaro, Spain). As a fail-safe, a 3D CAD/CAM surgical splint was ordered for every patient in the PSO group from KLS Martin (KLS Martin, Tüttlingen, Germany) in case the surgeon decided not to use the PSO for some reason during surgery. The patients in the control group received exactly the same 3D VSP work-up and, based on this, a 3D CAD/CAM surgical splint was also ordered.

The surgery included a conventional Le Fort I approach with an upper vestibular incision exposing the maxillary bone. In the PSO group, a separate left and right cut- and drilling guide was positioned, supported by the dentition and maxillary bone. The guides on the bone contour, fixed with a screw, indicated the Le Fort I osteotomy line as well as the drilling locations and directions for all the screws for the PSOs. Figure 1 provides a schematic overview of the 3D VSP (1A and B), the guide placement (1C) and the PSO in place (1D). The maxilla was mobilised and the PSOs were positioned over the pre-drilled screw holes and were fixed with commercially available 1.5 mm osteosynthesis titanium screws. An animation of the PSO concept is available online as a supplement to this manuscript. Figure 2 provides an overview of perioperative images of placement of the guides (2A), fixation of the PSOs (2B) and the final occlusion after completing the procedure (2C). The mandible of the bi-maxillary osteotomy cases was repositioned using a conventional bilateral sagittal split osteotomy guided by the final 3D printed splint. All cases where operated by a maxilla first approach.

Outcome measures

The primary outcome measure of this study was the median difference (in millimetres and degrees) between planned- and actual post-operative position of the maxilla in three planes. All the patients in this trial underwent a routine post-operative Cone Beam CT (CBCT) scan (FOV: 230x260mm, 0.4mm voxel size) at the first follow-up consultation (10 days after surgery).

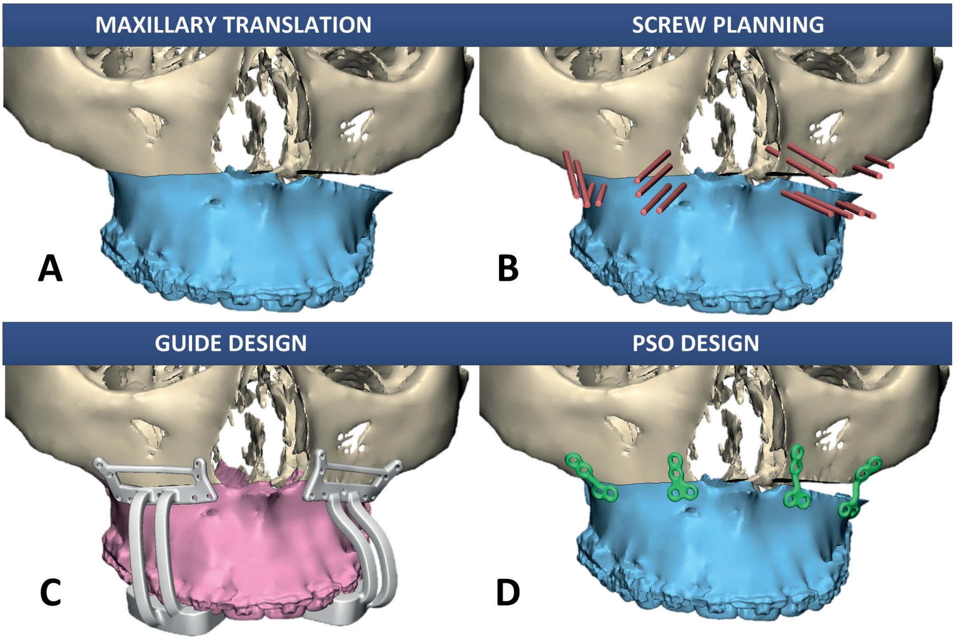

Figure 1: Schematic overview of the 3D VSP PSO workflow

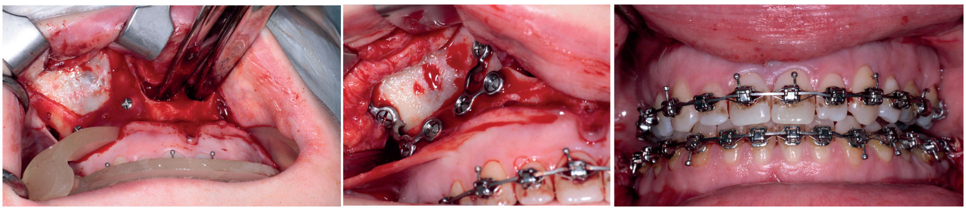

Figure 2: A. Intra operative placement and fixation of the drilling and cutting guide. B. PSOs positioned and fixed with miniscrews. C. Final occlusion after bimaxillary surgery.

A 3D virtual representation of the post-operative situation was registered to the 3D VSP in Maxillim v2.3 (Maxillim, Medicim, Mechelen, Belgium) using voxel-based matching [22]. A region of interest on the skull base, outside the surgically treated region, was selected for the matching.

The orthognathic analyzer (OGA) method, as reported by Baan et al. 2016, was applied to all cases to quantify the difference between the planned and actual post-operative position of the maxilla [23] by one observer (JK). The measured parameters were congruent to those used in the 3D VSP: anteroposterior-, cranial-caudal-, left-right translation at the central incisors, cranial-caudal translation at the first molars and pitch, yaw and roll in order to describe the rotational movement of the maxilla.

The secondary outcome measure was the reported surgical satisfaction. The surgeons applying the PSOs were asked to score the user friendliness of the guide and PSOs, as well as the position of the maxilla after completing the translation.

Statistics

The Mann-Whitney-U test was applied in order to compare the median and interquartile range of both groups for each parameter. The inter observer variation was determined for a randomly selected sample (N=5) analysed by a second observer (RS). Both observers (JK, RS) identified the landmarks and voxel-based registration of the data. The intraclass correlation coefficient (ICC) and the median and interquartile range were assessed to quantify the inter observer variation.

RESULTS

A total of 64 patients were included in the study, after informed consent. Of these patients, 58 completed the study protocol. Six patients were excluded from the PP analysis due to: late changes in surgical planning (n=1); damaged or incomplete guides or PSOs after sterilization (n=4); and per-operative conversion to the control group protocol (n=1). The PP PSO group included N= 27 patients and the control group N=31 patients. An additional ITT analysis was performed including the five patients that received the conventional treatment after conversion. For the ITT these patients were included in the intervention group. The demographics of the PSO- and the control groups are presented in Table 1.

Table 1: Patients' demographics per study group. Used abbreviations: SD= standard deviation.

Population (n=58)		Intervention (n=27)	Control (n= 31)
Age	Mean	27.6	29.5
	SD	10	9
	Range	19-60	19-51
Gender	Female (n=31)	12	19
	Male (n=27)	15	12

Table 2 presents the absolute differences between the planned and realized maxillary positions after PP analysis. The PSO group showed a smaller deviation from the planned position, compared to the control group, both at the level of the central incisors and first molars. The median absolute anteroposterior deviation was found to be 1.05mm (IQR: 0.45-2.72mm) in the PSO group and 1.74mm (IQR: 1.02-3.02mm) in the control group. Regarding the cranial-caudal deviation, the median was 0.87mm (IQR: 0.49-1.44mm) in the PSO group and 0.98mm (IQR: 0.28-2.10mm) in the control group. The left-right translation had a median of 0.46mm (IQR: 0.19-0.96mm) in the PSO group and 1.07mm (IQR: 0.62-1.55mm) in the control group.

The ITT analysis showed comparable median absolute values for the intervention group, the control group values were exactly the same as in the PP analysis. The median anteroposterior deviation was found to be 1.29mm (IQR: 0.57-2.76mm). Regarding the cranial-caudal deviation, the median was 0.91mm (IQR: 0.82-1.46mm). The left-right translation had a median of 0.45mm (IQR: 0.17-0.89mm).

The deviation from the planned maxillary position was found to be proportionally larger when the planned translation of the maxilla was larger. This effect was stronger in the control group, especially for the anteroposterior translation. Figure 3 presents a scatter plot in which all the calculated deviations from the planned anteroposterior translations are plotted against the actual value of the planned translation. The included regression line for both the PSO- and the control group demonstrates the difference in deviation between both groups. Applying the regression function to the regression lines in Figure 3 shows that a planned anteroposterior translation of >3.67mm led to >2.00mm deviation from the planning in the control group. The PSO group had a deviation of 1.39mm.

In addition, Figure 3 shows that the number of cases that deviated by >2.00mm from the planned position was smaller in the PSO group (33.30%) than in the control group (45.20%, p=0.35). Comparable results are found for the other translations. The cranial-caudal direction deviated (>2.00mm) by 3.70% of the cases in the PSO group and 25.80% in the control group (p=0.02). In the case of a left-right translation this (>2.00mm) was 3.70% for the PSO group and 9.70% for the control group (p=0.37).

The scatterplot presented in Figure 4 shows the deviation in craniocaudal direction. It is objectified that the amount of planned translation does not correlate with the deviation from planning, as both regression lines are flat. The scatterplot visualizes the difference in the amount of cases that deviate >2mm from the planned position between the PSO group (3.70%) and the control group (25.80%). The direction of craniocaudal translation

Table 2: Overview of the median deviation from the planned position of the maxilla, for the PSO and the control group.

		Intervention (n=27)			Control (n=31)			
Landmark	**Translation (mm)**	**Median**	**25th percentile**	**75th percentile**	**Median**	**25th percentile**	**75th percentile**	**p-value**
Upper Incisor	Left-Right	0.46	0.19	0.96	1.07	0.62	1.55	0.01*
	Anterior-Posterior	1.05	0.45	2.72	1.74	1.02	3.02	0.06
	Cranial-Caudal	0.87	0.49	1.44	0.98	0.28	2.10	0.81
1st Molar 16	Cranial-Caudal	0.50	0.19	0.72	0.53	0.32	1.38	0.30
1st Molar 26	Cranial-Caudal	0.46	0.16	0.71	1.02	0.38	1.72	0.01*
	Rotation (dgr)							
Pitch	CW/CCW	2.33	0.56	3.25	2.17	0.56	3.29	0.90
Roll	CW/CCW	0.53	0.23	0.81	0.60	0.19	1.23	0.35
Yaw	CW/CCW	0.21	0.06	0.29	0.44	0.07	1.31	0.06

The smallest deviation per landmark is in **bold**. Pitch represents a clockwise-counterclockwise rotation around the horizontal axis. Roll represents a clockwise-counterclockwise rotation around the anteroposterior axis. Yaw represents a clockwise-counterclockwise rotation around the craniocaudal axis. p* Represents a p-value <0.05 and thus a significant difference.

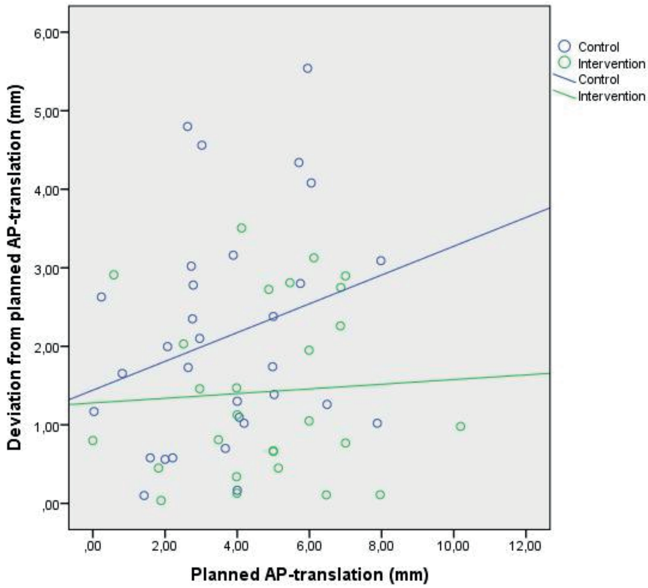

Figure 3: A scatterplot of the deviation from the planned anteroposterior translation of the PSO and control groups.

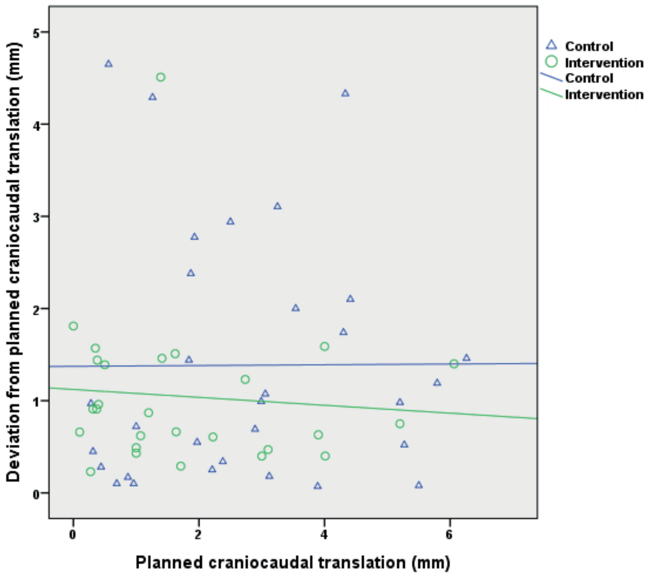

Figure 4: A scatterplot of the deviation from the planned craniocaudal translation of the PSO and control group.

can be differentiated in impaction and disimpaction. For the PSO group the median values are: 0.60mm (disimpaction) and 0.91mm (impaction) and for the control group: 0.45mm (disimpaction) and 0.78mm (impaction).

Interobserver variability

The ICC two-way mixed random was found to be 0.97 and the median difference between the observers was 0.42mm (IQR: 0.13-1.04mm).

Surgical satisfaction

The overall surgical satisfaction of the PSO method was rated as 7.8, from a scale of 0-10, by the surgeons on comparing the parameters with their experiences using conventional methods. The drilled screw holes (8.1), screw placements (8.1) and the position of the maxilla (8.4) were given an especially high score after PSO application in the questionnaire. Placement of the guide (7.5) and indication of the screw holes (7.1) scored lower.

DISCUSSION

This randomized controlled multi-centre trial compared the application of PSOs with a control group that received manually contoured OSM supported by 3D VSP splint-based maxillary positioning in Le-Fort I osteotomies. The 3D accuracy analysis shows that the use of PSOs in maxillary translations leads to a smaller deviation from the actual planned position compared to the use of conventional OSM and an intraoperative splint.

To our knowledge, our study is the first prospective randomized controlled multi-centre trial that objectifies the added value of PSOs in maxillary translations as part of orthognathic surgery. It was already reported by van den Bempt et al. 2018 that the use of PSOs have the highest potential for accurate transfer of the 3D VSP towards the actual surgical procedure [24].

Previous reports of the use of PSOs in orthognathic surgery have shown the advantages in terms of accuracy, independence of condylar seating and potential time-saving [15, 19]. Suojanen et al. 2018 reported that the use of a PSO does not introduce a difference in terms of required plate removal, infections or other soft tissue related problems [25]. No plates had to be removed in our study.

The largest population (N=32) was described by Suojanen et al. 2016, but no control group was included and no post-operative 3D accuracy analysis was performed[15].

Heufelder et al. 2017 reported a cohort study of 22 PSO patients. A post-operative accuracy analysis was performed with a surface-based registration which revealed deviations between 0-2.02mm from the planned position. Nonetheless, that study lacks systematic comparison with a conventional, splint based control group, as also acknowledged by the authors. Heufelder et al. stated that PSOs should be used for every maxillary positioning during orthognathic surgical procedures. Our study aims to objectify the added value of PSOs based on a randomized comparison, in order to define which maxillary translation actually benefits from PSO and which does not.

Several other studies reported the use of PSOs, however, these are small clinical cohort studies or case reports and also lack a systematic, randomized comparison with a conventional treatment group [16, 18].

Intra-operative navigation was reported as an alternative for splintless maxillary translation, instead of PSOs [1, 26, 27]. According to those studies, the accuracy of navigation is comparable to the use of splints, ranging from 0.28-1.99mm [10, 26] but the systems can be bulky and interfere with the surgeon's view and it is challenging to hold the maxilla in the correct position until the osteosynthesis material is applied [10]. Hence, it is our belief that PSOs provide a more rigid and predictable translation of the maxilla.

The guides used in our study are both tooth and bone borne resin based 3D prints [6]. Others have reported the advantages of bone borne titanium guides [19] such as providing a more rigid alignment and guidance for the drill. Resin based guides can deform somewhat when manual pressure is applied. On the other hand, once a small misfit occurs on one side of a one-piece titanium guide, it might introduce larger errors on the contralateral side. Furthermore, there is a potential difference in production costs between 3D printed resin based and titanium guides. It was beyond the scope of this study to objectify the cost-effectiveness of the PSO method or to compare it to the costs of other splintless methods.

Implications for current practice

As depicted in Figure 3, the deviation from planning, increases when the planned translation of the maxilla is larger. This is especially true for the control group which suggests that there is a stronger indication to use PSOs for larger translations. A reported clinically relevant cut-off deviation from the planning is 2mm [28-30]. As stated in the results section, a planned anteroposterior translation of 3.67mm or more will result in a deviation of 2mm when the control method is applied compared to a deviation of 1.39mm for the PSO group. This supports the use of PSOs when planning anteroposterior translations of 3.67mm (or in practice 3.70mm) and larger. A craniocaudal translation of the maxilla was reported to be the most difficult translation to achieve [19]. Our study shows that a PSO improves the craniocaudal positioning in comparison to the deviation found in the control group, although not statistically significantly (see Table 2). We note that the PSO method does not improve the impaction of the maxilla, possibly due to the bony interferences that need to be removed by the surgeon. Moreover, the removal of interferences was easier with conventional splint-based positioning than with PSOs, as was reported by the surgeons in our study.

Recommendations for future studies

A comparison by Liebregts et al. (2017) of maxilla-versus mandible first approaches indicated that the maxilla first approach is generally the most accurate [9]. However, the mandible first approach is indicated for a pitch in a counter clockwise direction. Our study found that there is hardly any difference between the PSO (median 2.17 degrees) and the control (median 2.33 degrees) group in terms of absolute pitch deviation. This suggests that a prospective comparison between PSO and a mandible first approach, using splint based maxillary positioning, should be performed for this indication.

Additional subgroup analysis is required in order to objectify if specific subgroups benefit from the use of PSOs, such as 2 or 3 segmental osteotomies of the maxilla since they were not included in the current study.

CONCLUSION

The use of PSO is indicated for large planned translations, especially anteroposterior translations larger than 3.70mm. This study proves that PSO is an easy to use method that improves the accuracy in maxillary translation in orthognathic surgery.

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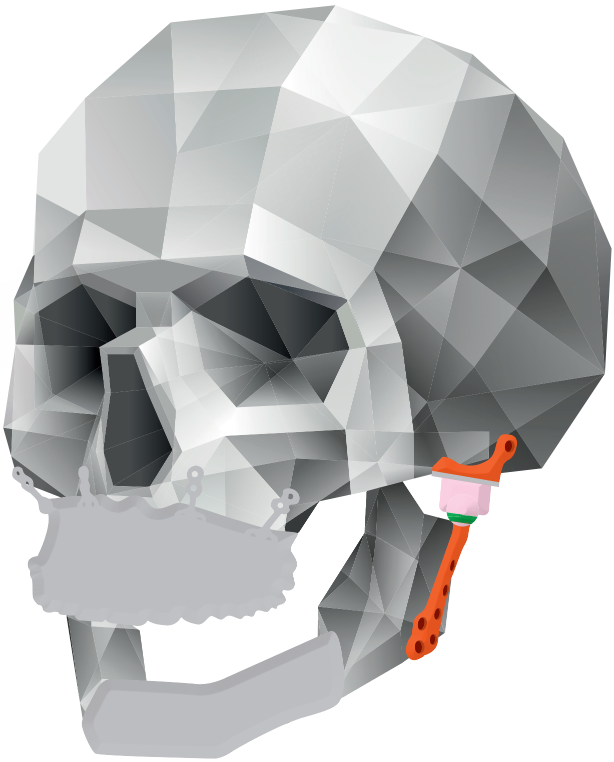

PART III

TEMPOROMANDIBULAR JOINT SURGERY

3D Interactive Model

TEMPOROMANDIBULAR JOINT SURGERY

Please click the buttons to activate the predefined 3D views.

Screw Planning

Guide Design

Condylectomy

Screw Holes

TMJ Prosthesis